DETAILED ACTION

Response to Amendment

1. The amendment filed 08/29/2011 has been entered. Currently claims 2-6, 9, 12, and 20-24 are pending and claims 1, 7, 8, 10, 11, and 13-19 are cancelled.

2. Claim 2 is objected to because of the following informalities:

In claim 2, the phrase "wherein the unitary cover layer includes a titanium nickel alloy, and wherein the metal forming the carrier structure is the titanium nickel alloy" is objected to grammatically. The objection can be overcome by changing the limitation to "wherein the metal or metal compound in the unitary cover layer includes a titanium nickel alloy, and wherein the metal forming the carrier structure is the same titanium nickel alloy" which is how the phrase will be interpreted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 2-6, 9, 12, and 20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 2, 6, 9, 20, 21, and 23, the Examiner does not find support to claim a "unitary core marker element" in the specification as originally filed. The marker element is not unitary as seen in Figure 3 as the comparatively radiopaque material and the cover layer that make up the marker element are not a unitary material. This rejection can be overcome by changing the limitation back to "marker element" and addressing the rejection set forth in section 4 below.

4. Claims 2-6, 9, 12, and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 2, 6, 9, 20, 21, and 23, it is unclear how the marker element is "unitary core marker element", and yet is made from a comparatively radiopaque material and a cover layer that are two separate materials; hence, not unitary. As seen in Figure 3 the comparatively radiopaque material and the cover layer that make up the marker element are not a unitary material. For purposes of examination, this limitation will be treated as a "marker element including a unitary core of a comparatively radiopaque material".

With regard to claim 5, it is unclear if the silicon carbide is in the same cover layer as the titanium-nickel alloy or if it is a coating on the titanium nickel alloy cover layer. For the purposes of examination, the claim will be interpreted as silicon carbide mixed with the titanium nickel alloy of the cover layer.

Claim Rejections - 35 USC § 103

5. Claim 2-4, 6, 9, 12, 20, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kranz et al. (6,312,456) in view of Callol et al. (EP 1290984).

With regard to claims 2-4, 6, 9, 12, 20 and 22-24, Kranz et al. disclose the stent of Figure 1.

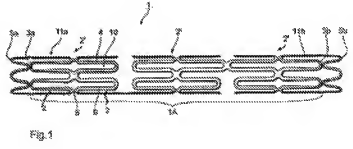

Fig.1

The stent **1** has a hollow-cylindrical base body **1A** made from titanium that is produced from hollow-cylindrical tube rounds, which reads on applicants' partially radiolucent carrier structure (col. 2, lines 38-42 and col. 3, lines 23-26). The web-like elements **9** (also frontal mesh curve **3a**) form a ring-shaped design that reads on applicants' plurality of legs (col. 3, lines 28-31). There is an X-ray opaque thread **5a** welded onto the end of the cylinder (col. 3, lines 46-51). The X-ray opaque material can be gold (col. 2, lines 32-37). The structure may be covered with a silicon carbide coating (col. 2, lines 51-54). A stent will intrinsically be implanted into a patient to treat them as that is

what stents are intended to perform; however, they do not disclose that the carrier structure is a nitinol alloy or that the cover layer is a nickel-titanium alloy.

Callol et al. disclose forming a radiopaque material on a stent. The entire stent then may be coated with a protective layer **34** [0051]. This is done to prevent galvanic corrosion at the joined region of the elongated carrier structure and the radiopaque material [0012]. The carrier structure may be nickel-titanium alloy [0013], which reads on applicants' self-expanding carrier structure of a shape memory metal, the radiopaque layer may be gold [0053], and the protective layer may be a titanium alloy [0020]. The radiopaque layer may be welded to the strut [0011].

Since Kranz et al. and Callol et al. are drawn to radiopaque marking of stents; it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the carrier structure of Kranz et al. from nitinol and to have covered the entire carrier structure with a titanium alloy as taught by Callol et al.; furthermore, it would have been obvious to one having ordinary skill to have used the same titanium-nickel alloy, i.e. nitinol, as was used to form the carrier structure to form the protective layer. The rationale to use the protective layer is to prevent the radiopaque layer and the elongated tubular body from galvanic corrosion and to protect the layers from mishandling [0012]. The rationale to use the same material is that it would save on costs in producing the stent as the same material for the carrier structure was being used for the protective layer.

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kranz et al. (6,312,456) in view of Callol et al. (EP 1290984) as applied to claim 2, and further in view of Flanagan (WO 01/45578).

Kranz et al. in view of Callol et al. render obvious all of the limitations of claim 2 in section 5 above; however, they do not disclose a marker element is welded into an aperture created by cutting out a leg.

Flanagan teaches in Figures 6 and 2B making a weld **50** of a radiopaque marker **32** made of a second metal **22** to the first metal **20** that makes up the stent **31** (page 11, lines 5-11).

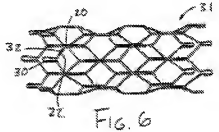

FIG. 6

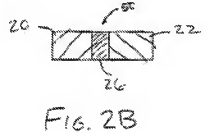

FIG. 2B

The first metal may be nitinol, which is a titanium-nickel alloy shape memory metal that would be capable of self-expanding, and the second metal may be gold (page 7, lines 6-9). This reads on applicants' marker element welded into an aperture created by cutting out a leg.

Since Kranz et al. in view of Callol et al. and Flanagan are drawn to radiopaque marking of stents; it would have been obvious to one having ordinary skill in the art at the time the invention was made to have welded a gold marker element into the stent as shown by Flanagan. The rationale to use this welded type structure is that it provides a strong bond and prevents movement of the marker when the stent is deployed (page

11, lines 12-22). The resultant structure would then be coated with the silicon carbide coating as taught by Kranz et al. to prevent thrombosis formation, and the gold radiopaque marker coated by SiC would remain a core filled wire as claimed.

Response to Arguments

7. Applicant's arguments, see Remarks, filed 08/29/2011, the objections to claims 1, 3-6, 9, 11, 12, and 20-24 and the rejections based upon Callol et al. Dang as primary references have been fully considered and are persuasive. The relevant objections/rejections have been withdrawn.

Upon reconsideration, the Dang reference would not have a unitary cover layer as claimed because there would necessarily have to be some seam or bonding region formed in the sputtering reaction.

Callol et al. is withdrawn based upon the interpretation of claim 2 as set forth in the rejections under 35 USC 112, second paragraph. Callol et al. do not teach the unitary core being the comparatively radiopaque material.

8. Applicant's arguments filed 08/29/2011 have been fully considered but they are not persuasive.

The Examiner will respond to applicants' arguments as they pertain to Kranz et al. as the primary reference.

Applicants' argue on page 10 of their Remarks that Kranz et al. do not teach forming the unitary core marker element with the unitary cover layer.

The Examiner respectfully disagrees and notes that the stent rendered obvious in this rejection would have had the base structure of Figure 1 of Kranz et al. be made of the carrier structure material of Callol et al., i.e. the titanium nickel alloy, with the gold marker elements. The rejection also sets forth that it would have been obvious to have coated the entire carrier structure with a layer of titanium-nickel alloy as taught by Callol et al. to prevent galvanic reactions at the gold and titanium-nickel bonding sites. The resultant structure has a unitary core of the radiopaque material having a unitary cover layer of the titanium-nickel alloy claimed. This rejection is still valid and has been reformulated as necessitated by applicants' amendments to also include claims 2-4, 6, 9, 12, and 22-24 for the same rationale. Applicants appear to be arguing the references individually when the rejection is based upon the combination of references.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERARD HIGGINS whose telephone number is (571)270-3467. The examiner can normally be reached on M-F 10am-8pm est. (Variable one work-at-home day).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Ruthkosky can be reached on 571-272-1291. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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